

Overview of the MIRIAD Project

Marc Bulterys

**Division of HIV/AIDS Surveillance and Epidemiology
Centers for Disease Control and Prevention**

The objectives of the Mother Infant Rapid Intervention at Delivery (MIRIAD) project are:

- ! to evaluate innovative approaches to counseling and voluntary rapid HIV testing for women in labor with unknown HIV status.
- ! to assess the feasibility of obtaining informed consent during labor or soon after birth.
- ! to describe barriers to HIV testing and reasons for lack of prenatal care.
- ! to assess rapid delivery of antiretroviral prophylaxis to late presenters.
- ! to evaluate neonatal therapy adherence and receipt of post-natal care for women identified as HIV-infected.

The MIRIAD project is limited to institutions with relatively high HIV prevalence (0.8 - 4 %) among childbearing women. There are five primary sites: Atlanta, Chicago, Miami, New Orleans, and New York City.

Funding was initially awarded for four years, and project development began in October 1999. The first year was devoted to uniform protocol development across all five sites. The second year was dedicated to obtaining multiple institutional review board approvals, piloting the informed consent process in labor, and obtaining a treatment investigational device exemption from the Food and Drug Administration for the use of a non-licensed rapid HIV assay. In the third and fourth years, the project will be expanded to other hospitals in the same geographic area.

Enrollment in the MIRIAD study started at two sites -- Chicago and Miami -- in mid-November, 2001. A total of 14 hospitals from the five sites will be participating in the MIRIAD study by midsummer 2002. Project sites will link collaboratively with Pediatric AIDS Clinical Trials Group protocols.

The biomedical research priorities of MIRIAD include:

- ! evaluating rapid HIV testing algorithms.
- ! conducting virologic sub-studies (e.g., nasal/oral suction material for polymerase chain reaction detection of HIV).
- ! assessing antiretroviral drug resistance among infected infants and drug-naïve HIV-positive women.
- ! investigating the mechanism of action of AZT and NVP prophylaxis.
- ! evaluating adherence to neonatal therapy.
- ! studying host-related genetic factors and HIV transmission.

The behavioral research issues are:

- ! to assess feasibility of informed consent during labor, and retention post-delivery.
- ! to determine reasons for lack of prenatal care, or barriers to obtaining this care.
- ! to measure perceived social support and psychosocial assets in mothers.
- ! to determine factors predicting foster care referral.
- ! to describe patterns of adherence to antiretroviral therapy in women and their children.
- ! to evaluate an intervention to improve adherence to neonatal prophylaxis through a modified directly-observed therapy.

At each site, a minimum of 1,000 women presenting with unknown HIV status late in pregnancy will be screened using the Oraquick rapid HIV assay (approximately 6,000/year across sites). We expect each site will identify and enroll approximately 20 B 30 HIV-1 infected women into the MIRIAD rapid intervention protocol and mother-infant follow-up (a total of 100 B 140/year across sites).

Three subgroups of HIV-positive women and their infants will be enrolled into the MIRIAD intervention protocol: women presenting in labor; late-registrant mothers ≥ 34 weeks of gestational age; and women identified with primary HIV infection. At labor and delivery, the MIRIAD study will evaluate the ability to obtain test samples and do rapid HIV testing in the laboratory and/or at the bedside, the rapidity with which results are available, and the efficiency of ordering and administering antiretroviral medication.

MIRIAD will also employ a behavioral postpartum intervention designed to support recently-identified HIV-infected mothers to focus their attention on following HIV therapeutic guidelines for themselves and their exposed children. It is hoped that results from these studies will lead to best practice recommendations on rapid HIV testing and administration of antiretrovirals among late-registrant women.

###